510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 807.92(c).

Owner Name: Boston Scientific Corporation

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Lowell, MA 01851

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Date of Summary: 2 May 2014

Device Trade Name: LabSystem™ PRO EP Recording System

Device Common Name: Programmable Diagnostic Computer

Classification Name: Programmable Diagnostic Computer

Product Code: DQK

Predicate Device(s): Bard LabSystem PRO EP Recording System (K031000/June 3, 2003)

V2.6 Software for the Bard LabSystem PRO EP Recording System (K113811/April 3, 2012)

Device Description:

The V2.7 software for the LabSystem™ PRO EP Recording System is substantially similar to the currently commercialized software (V2.6a) with the difference that the V2.7 software runs on a Microsoft Windows 7 platform as compared to V2.6a which runs on a Windows XP platform. Other than the platform update, there are no changes to the LabSystem PRO EP Recording System software functionality. There are no changes to the fundamental scientific technology of the device nor are there any changes to the intended use.

The LabSystem™ PRO EP Recording System is a microprocessor based data acquisition system that is used during electrophysiology procedures to acquire ECG, intracardiac, pressure and digital data from other devices like fluoroscopic systems and RF generators. The ECG, intracardiac and pressure data are acquired by an amplifier that is connected to the patient via ECG leadwires and catheters. It does not transmit alarms and does not have arrhythmia detection capabilities.

Indications for Use:

The LabSystem EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.

When integrated with the Biosense Webster® CARTO™ 3 system, the Bard® LabSystem™ PRO EP Recording System is designed to: a) send patient demographics to Biosense Webster® CARTO™ 3, and b) acquire (from Biosense Webster® CARTO™ 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense

Webster® CARTO™ 3 device and stored on the Bard® LabSystem™ PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection and information sharing between the two systems.

Comparison to Predicate Devices:

The predicate devices for this 510(k) Premarket Notification are the LabSystem™ PRO EP Recording System (K031000), and the V2.6 Software for the LabSystem PRO EP Recording System (K113811). The Indications for Use between the V2.6 software and the proposed software, V2.7, are identical.

All of these devices are electrophysiology recording systems that are used for the same intended purpose. These systems are intended for use under the direct supervision of a licensed healthcare practitioner to acquire, filter, digitize, amplify, and record electrical signals obtained during electrophysiological studies and related procedures conducted in an electrophysiological laboratory. The systems acquire signal types which include ECG signals, direct cardiac signals, and pressure recordings. The systems obtain physiological parameters such as diastolic, systolic and mean blood pressure, heart rate and cycle length which are derived from the signal data, displayed and recorded. The systems allow the user to monitor the acquisition of data, review the data, store the data, perform elementary caliper-type measurements of the data and generate reports on the data. The systems acquire, amplify, display and record data received from other medical devices typically used during these procedures, such as imaging devices and RF generators. The systems do not transmit alarms and do not have arrhythmia detection capabilities.

V2.6 software (K113811) and the proposed V2.7 software have the capability to integrate with the Biosense Webster®, CARTO™ 3 system, to send patient demographics to Biosense Webster® CARTO™ 3, and acquire (from Biosense

Webster® CARTO™ 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense Webster® CARTO™ 3 device and stored on the Bard® LabSystem™ PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection between the two systems.

The hardware, base software and firmware that are currently utilized in the LabSystem PRO EP Recording System (K031000 and K113811) are substantially equivalent to the base software and firmware for the V2.7 software for the LabSystem PRO EP Recording System.

Summary of Non-Clinical Testing:

The LabSystem™ PRO EP Recording System is developed and produced in accordance with 21 CFR 820.30 Quality System Regulations. The software product is developed and tested in accordance with the following industry standards. Use of the IEEE standards is voluntary.

IEEE Standard 730-2002	Software Quality Assurance Plans
IEEE Standard 829-2008	Software Test Documentation
IEEE Standard 1012-2012	Software Verification and Validation Plans
IEEE Standard 830-1998	Software Requirement Specifications
IEEE Standard 1008-1987	Software Unit Testing

EN 60601-1-2:2007	EMC, Radiated emissions and Conducted emissions requirements
EN 60601-1:2005	Patient Leakage current (Section 19, Table IV, Type CF, 50uA)
IEC 62304:2006	Medical Device Software – Software Life Cycle Processes

Software qualification is performed in-house on the System with results that meet acceptance criteria, thus confirming the safety and effectiveness of each functional aspect of the LabSystem™ PRO EP Recording System.

Substantial Equivalence:

The LabSystem™ PRO EP Recording System, subject of this 510(k), is substantially equivalent to the predicate devices. They have the same Indications for Use and principles of operation, and the technological characteristics support a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Boston Scientific Corp.
Ms. Robin Mulvey
Regulatory Affairs, Specialist II
55 Technology Drive
Lowell, Massachusetts 01851

Re: K141185
Trade/Device Name: LabSystem™ PRO EP Recording System V2.7
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 5, 2014
Received: May 7, 2014

Dear Ms. Mulvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

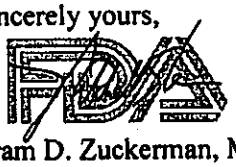
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K141185

Indications for Use

510(k) Number (if known):

Device Name: LabSystem™ PRO EP Recording System

Indications for Use:

V2.7 software for the LabSystem™ PRO EP Recording System Indication: The LabSystem™ EP Laboratory is a computer and software driven data acquisition and analysis tool designed to facilitate the gathering, display, analysis by a physician, pace mapping and storage of cardiac electrophysiologic data.

When integrated with the Biosense Webster® CARTO™ 3 system, the Bard® LabSystem™ PRO EP Recording System is designed to: a) send patient demographics to Biosense Webster® CARTO™ 3, and b) acquire (from Biosense Webster® CARTO™ 3), store and display: i) synchronized 3D mapping events, ii) stimulation pacing data, and iii) images of completed 3D electro-anatomical maps of the human heart. The 3D mapping events and images are created by the Biosense Webster® CARTO™ 3 device and stored on the Bard® LabSystem™ PRO EP Recording System for review and insertion into the final clinical report. Integration also supports bidirectional communication of stimulation pacing channel selection and information sharing between the two systems.

Contraindications: None

Prescription Use ___√___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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